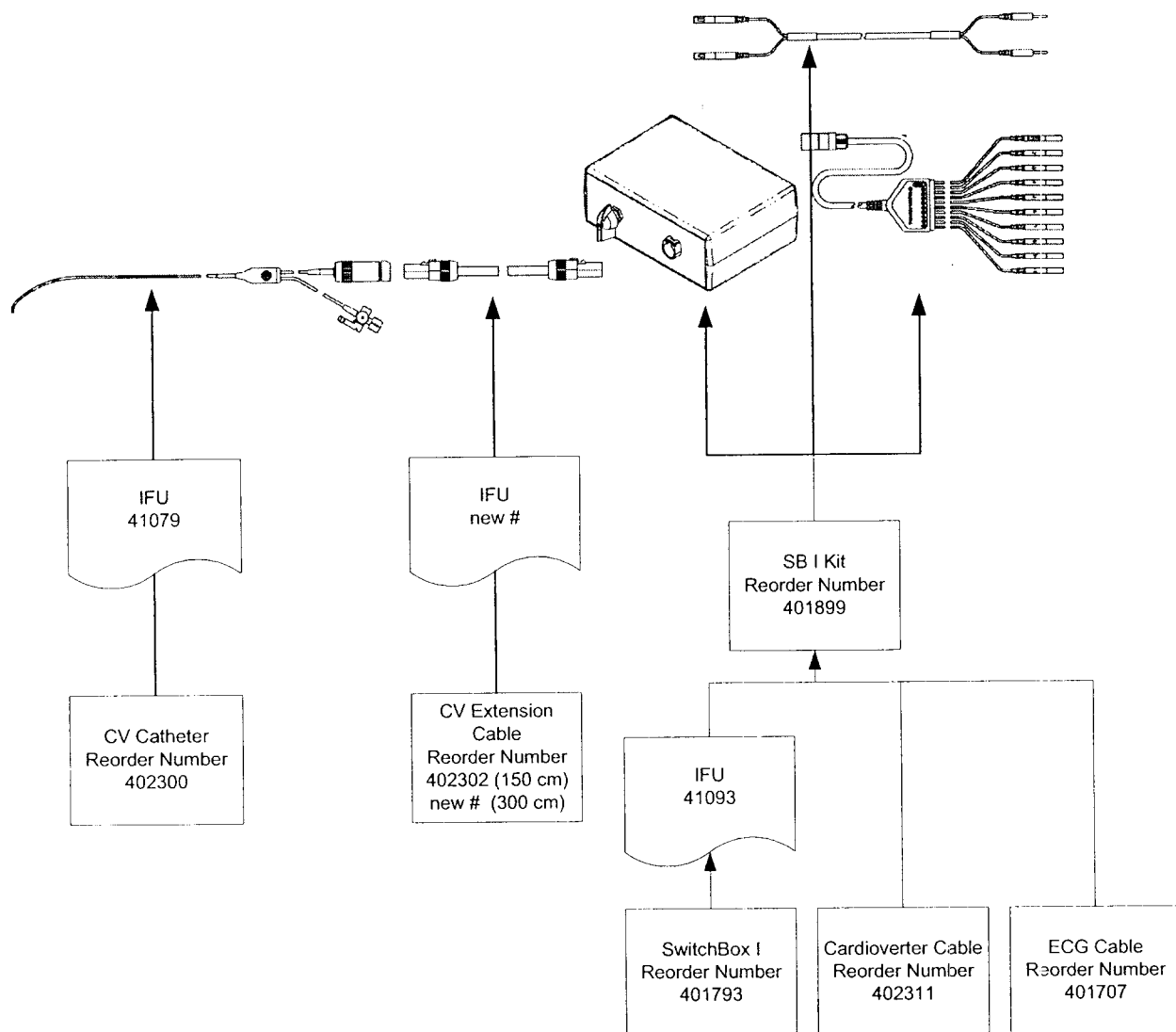


## Response CV IFU Flowchart





## CARDIOVERSION SWITCHBOX SYSTEM

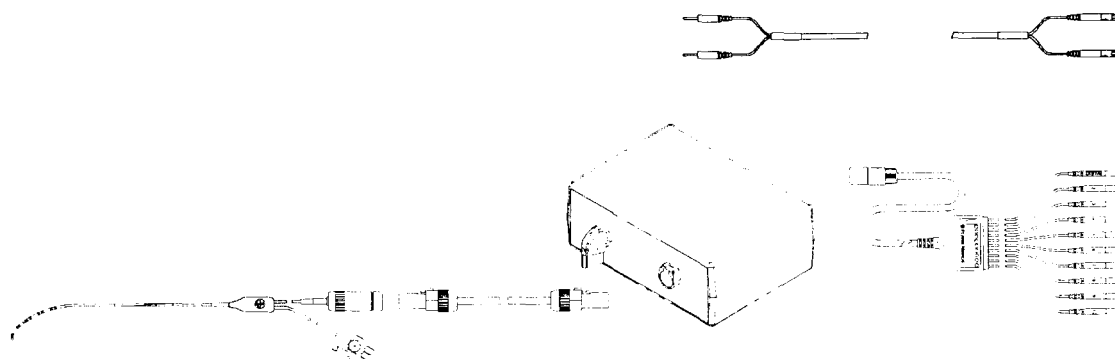
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Refer to **SYMBOL** section for definition of symbols.

## DEVICE DESCRIPTION

The St. Jude Medical (SJM) Cardioversion Switchbox System directs energy from a compatible cardioverter to a SJM Cardioversion (CV) catheter (ordered separately) for internal cardioversion of atrial fibrillation or other supraventricular tachycardias (SVT). It allows the CV catheter to be switched between routine diagnostic electrophysiology (EP) and cardioversion functions. The system includes a non-powered switchbox, catheter, and cables (ordered separately), as pictured below:



### **SJM Cardioversion Switchbox System**

## INDICATIONS FOR USE

The SJM Cardioversion Switchbox System is intended to connect a SJM Cardioversion Response™ (CV) Electrophysiology Catheter and SJM Electrophysiology CV Extension Cable to a compatible cardioverter/defibrillator and EP recording system.

The SJM Cardioversion Cables are intended to connect to the SJM Cardioversion Switchbox System.

## CONTRAINDICATIONS

- DO NOT use this device with a cardioverter designed for transthoracic (external) cardioversion.

## WARNINGS

- This device must be used with a cardioverter designed for internal cardioversion. Use of a cardioverter designed for external cardioversion could cause severe injury or death.

## PRECAUTIONS

- DO NOT alter this device.
- Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- Only physicians thoroughly trained in the techniques of intracardiac recording, stimulation and cardioversion should use this device.

- This device should only be used with equipment that complies with international safety standards.
- Limit cardioverter output through this device to 50 joules or less.
- Use this device with SJM "CV" catheters only. Use with SJM catheters not designated "CV", or catheters from other vendors, may be ineffective and/or hazardous to patients and medical staff.
- Use only SJM cables designed for this system.
- Contents of this Instruction For Use must be read and understood before using this device.
- Contents of the compatible cardioverter Instruction and/or Operator's Manual must be read and understood before using this device.
- Contents of the Instructions For Use for the CV catheter and the CV Electrophysiology Extension Cable must be read and understood before using this device.
- Store in a cool, dark, dry place.

#### HOW SUPPLIED

The following items make up the SJM Cardioversion Switchbox System; each is ordered separately:

1. Cardioversion Switchbox Kit which includes:

- Cardioversion Switchbox
- Cardioversion Switchbox Electrogram Output Cable
- Cardioverter Cable

2. CV Catheter

3. CV Electrophysiology Extension Cable

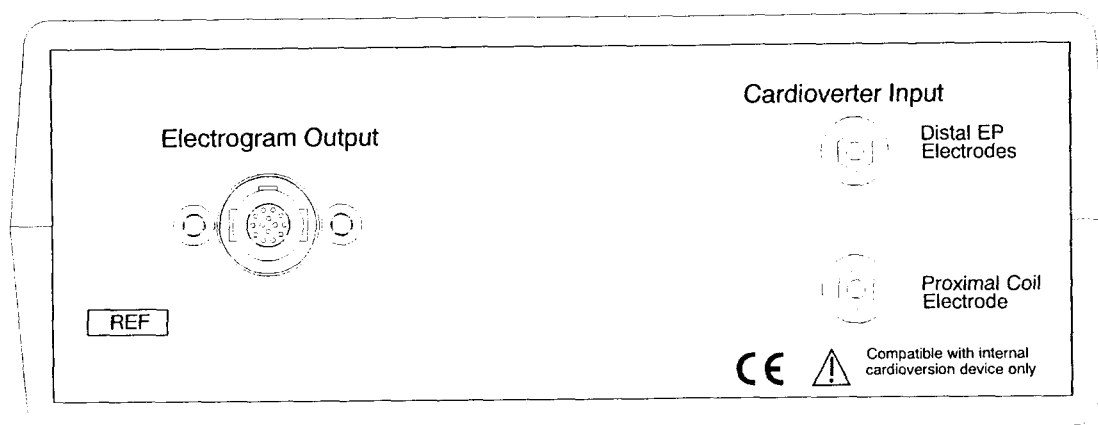
Carefully unpack all items of the SJM Cardioversion Switchbox System. Inspect each item for damage. Immediately report any problems and concerns to SJM Corporation.

## INSTRUCTIONS FOR USE

The Cardioversion Switchbox can be secured to a surface with the enclosed fastener strips to prevent damage during the procedure.

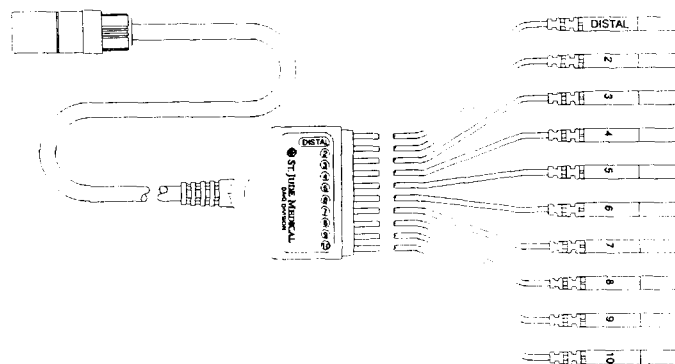
**CAUTION:** Use only SJM cables designed for this system.

Once the Cardioversion Switchbox is in place, the Cardioversion Switchbox System cables can be connected. Receptacles for these cables are located on the rear panel of the Cardioversion Switchbox, as pictured below.



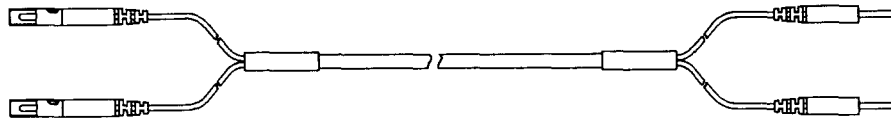
### **Rear Panel of Cardioversion Switchbox**

A SJM Cardioversion Electrogram Output Cable (pictured below) connects the SJM Cardioversion Switchbox to an amplifier/junction box. This cable passes signals from the SJM CV Catheter via the Cardioversion Switchbox to the amplifier (see the "Principles of Operation" section of this manual for a complete explanation of this function). Insert the single end of the Cardioversion Switchbox Electrogram Output Cable into the receptacle labeled "Electrogram Output" on the rear panel of the Cardioversion Switchbox. Connect the other end of this cable to the amplifier/junction box per manufacturer's instructions.



### **Cardioversion Switchbox Electrogram Output Cable**

The SJM Cardioverter Cable (pictured below) connects the SJM Cardioversion Switchbox to a compatible cardioverter. This cable directs cardioversion energy from a cardioverter to the SJM CV catheter via the Cardioversion Switchbox. (see the “Principles of Operation” section of this manual for a complete explanation of this function).



### **Cardioverter Cables**

#### **WARNING**

- This device must be used with a cardioverter designed for internal cardioversion. Use of a cardioverter designed for external cardioversion could cause severe injury or death.

The cardioverter cable, color-coded red (positive) and black (negative), directs the cardioversion energy from the cardioverter to the Cardioversion Switchbox. Attach the shrouded connector pins of the cardioverter cable to the cardioverter. (NOTE: See the adapter manual and supplement for assembly instructions of the supplied adapters.) The red shrouded connector is typically secured to the “positive” high voltage output receptacle of the compatible cardioverter and the black shrouded connector to the “negative” high voltage output receptacle. After these connectors are secure on the cardioverter, insert the opposite ends of the cable into the receptacles of the Cardioversion Switchbox labeled “Distal EP Electrodes” and “Proximal Coil Electrode” according to the desired polarity.

Once the SJM Cardioversion Switchbox has been secured and all cables have been connected, the system is ready for use.

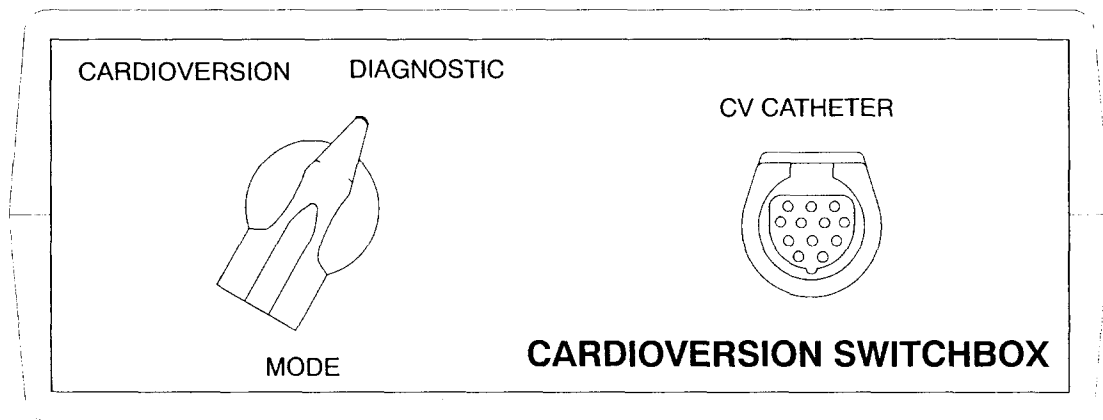
#### **Principles of Operation**

The SJM Cardioversion Switchbox System has two operational modes:

1. Diagnostic Mode
2. Cardioversion Mode

In "Diagnostic Mode" the distal electrodes function independently so that the CV catheter can be used as a conventional coronary sinus electrophysiology catheter. The Cardioversion Switchbox passes signals from the distal electrodes of the CV catheter to the amplifier/recording system via the "Electrogram Output" receptacle.

In "Cardioversion Mode" the Cardioversion Switchbox electrically connects all of the distal electrodes of the SJM CV catheter so they function as a single pole of the cardioversion circuit. The proximal coil electrode of the catheter functions as the other pole of the cardioversion circuit. Cardioversion current traverses both atria by travelling between the distal electrodes positioned in the coronary sinus and the proximal coil electrode positioned against the lateral wall of the right atrium.



**Front Panel of Cardioversion Switchbox**

### **Study Preparation and Diagnostic Mode**

In this mode the CV catheter functions as a traditional coronary sinus catheter. The Cardioversion Switchbox passes untreated signals from the distal EP electrodes of the CV catheter to the amplifier/recording system via the "Electrogram Output" receptacle.

1. This mode is initiated by placing the "Mode" switch in the "Diagnostic" position.
2. Secure a sterile CV Electrophysiology Extension Cable (pictured below and ordered separately) to the CV Catheter receptacle on the front panel of the Cardioversion Switchbox. **Note:** Both ends of this cable are identical. Therefore, either end may be plugged into the CV Catheter receptacle.



**CV Electrophysiology Extension Cable**

3. Position a sterile SJM CV catheter (ordered separately) in the coronary sinus using standard techniques.
4. Connect the CV catheter to the CV Electrophysiology Extension Cable.
5. Observe signals on the amplifier/recording system monitors and reposition the CV catheter as required.

#### Cardioversion Mode

Perform cardioversion according to the following:

1. Adjust the amplifier/recording system as necessary to display electrograms from other electrophysiology catheters. Electrograms will not be available from the CV catheter with the "Mode" switch in the "Cardioversion" position.
2. Place the "Mode" switch in the "Cardioversion" position.
3. Select the cardioverter parameters according to the manufacturer's instructions. Be sure to set the cardioverter output level to 50 joules or less.
4. Perform synchronized cardioversion.
5. Immediately following shock delivery return the "Mode" switch to the "Diagnostic" position in order to observe electrograms from the CV catheter.

#### At the Conclusion of the Study

1. Confirm the "Mode" switch is in the "Diagnostic" position.
2. Disconnect the CV Electrophysiology Extension Cable from both the Cardioversion Switchbox and the CV catheter, and process per hospital procedures.
3. Remove and discard the CV catheter per hospital procedures.

#### CLEANING

Do not immerse any of the SJM Cardioversion Switchbox System components in liquid. Unless otherwise indicated, do not sterilize any of the components of the SJM Cardioversion Switchbox System.

#### SPECIFICATIONS

##### Cardioversion Switchbox

- Dimensions: 5.8 cm (2.25 in.) x 15.3 cm (6.00 in.) x 10.8 cm (4.25 in.)
- Weight: 0.32 kg (0.7 lbs.)
- Maximum cardioverter energy: 50 joules
- Acceptable catheters: Use SJM "CV" catheters and extension cables only

##### Compatible Cardioverter Requirements

- Maximum Power Output: 50 joules
- Synchronous shock delivery
- Mono-phasic or Biphasic waveform output
- High voltage output connectors compatible with shrouded 2 mm pins



#### Cardioversion Switchbox Electrogram Output Cable

- Configuration: Decapolar
- Length: 150 cm

#### Cardioverter Cable

- Length: 150 cm
- Length: 300 cm

### TROUBLESHOOTING

#### **Problem**

Cardioversion energy is not being delivered.

#### **Possible Solution**

- Check that the “Mode” switch is in the “Cardioversion” position.
- Verify that all cables are properly connected.
- Confirm that a SJM CV catheter is being used.
- Verify proper function of the cardioverter.

Electrograms are not being acquired from the CV catheter.

- Check that the “Mode” switch is in the “Diagnostic” position.
- Verify that all cables are properly connected.
- Verify proper function of the recording system.
- Confirm the CV catheter is properly positioned in the coronary sinus.

**SYMBOL**

– Definition of symbols.



– Store in a cool, dark, dry place.

**LOT**

– Lot Number

**REF**

– Reorder Number or Catalog Number

**CONTENTS**

– Contents of the package



– Caution, consult accompanying documents.

**LENGTH**

– Useable length of the device.



### LIMITED WARRANTY AND DISCLAIMER

St. Jude Medical, Daig Division, Inc. ("SJM") hereby warrants that if any SJM product fails to perform within normal tolerances for a period of 12 months from date of purchase due to a defect in materials or workmanship, SJM will replace the system components free of charge. This limited warranty applies only if each of the following conditions are met:

1. The product was packaged and labeled by SJM .
2. The product has not been mishandled, reprocessed or altered in any way.

No representation or warranty is made that a SJM product will not fail. SJM disclaims responsibility for any medical complications, including death, resulting from the use of its products. Except as expressly provided by this limited warranty, SJM IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF ITS PRODUCTS, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE. Some states do not allow the exclusion or limitation of incidental or consequential damages however, so the above limitation or exclusion may not apply to you.

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## **Response<sup>™</sup> CV**

### **ELECTROPHYSIOLOGY EXTENSION CABLE**

#### **Instructions for use**

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Refer to **SYMBOL** section for definition of symbols.

RESPONSE™ CV  
ELECTROPHYSIOLOGY EXTENSION CABLE

DEVICE DESCRIPTION

Electrophysiology catheter extension cable.

INDICATIONS FOR USE

- SJM "CV" Electrophysiology Extension Cables is intended to connect a SJM Response™ CV Cardioversion Electrophysiology Catheter to a SJM Cardioversion Switchbox System.

CONTRAINDICATIONS

- There are no known contraindications for this device.

PRECAUTIONS

- DO NOT alter this device.
- Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- Only physicians thoroughly trained in the techniques of intracardiac recording, stimulation and cardioversion should use this device.
- This device should only be used with equipment that complies with international safety standards.
- This device should only be used with SJM Response™ CV catheters and SJM Cardioversion Switchboxes.

CLEANING AND TESTING PRIOR TO STERILIZATION

The cable should be thoroughly cleaned with mild detergent solution or 70% isopropyl alcohol and rinsed with clean water.

After cleaning, the cables should be inspected by qualified personnel for deterioration and proper cable function.

PACKAGING AND ETO STERILIZATION

Package the cable in a container (e.g. Tyvek pouch) appropriate for sterilization and storage.

Sterilize in an Ethylene Oxide (EtO) Sterilizer with a sterilization cycle validated to insure sterility.

SJM experience indicates that the cable can be cleaned as indicated above and re-sterilized up to five times in EtO cycles with 50–60% RH, 400 mg/L minimum EtO concentration, 125–135° F (52–57° C) and 8–10 PSI (55–69 kPa) for 5 hours minimum.

The cleaning, inspection and sterilization procedures described were determined by using SJM equipment and facilities. If you re-sterilize, these procedures must be validated for effectiveness in your facility. This validation for effectiveness should include a method for determining sterility such as biological indicators.

**SYMBOL**

– Definition of symbols.



– Store in a cool, dark, dry place.

**LOT**

– Lot Number

**REF**

– Reorder Number or Catalog Number

**CONTENTS**

– Contents of the package



– Caution, consult accompanying documents.

**LENGTH**

– Useable length of the device.

**STERILE EO**

– Sterilized using ethylene oxide.



– Date of manufacture or Sterilized on.



– Use before





## LIMITED WARRANTY AND DISCLAIMER

St. Jude Medical, Daig Division, Inc. ("SJM") hereby warrants that if any SJM product fails to perform within normal tolerances for a patient due to a defect in materials or workmanship, SJM will provide, at no charge, a replacement SJM product for the patient's use. This limited warranty applies only if each of the following conditions are met:

1. The product was packaged and labeled by SJM .
2. The failed product must be returned to SJM and becomes the property of SJM .
3. The product has not been mishandled, reprocessed or altered in any way.
4. The product was used before the "USE BEFORE" date marked on the packaging of the product.

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## INSTRUCTIONS FOR USE

### **Response™ CV** **CARDIOVERSION ELECTROPHYSIOLOGY** **CATHETER WITH LUMEN**

Read Instructions for Use prior to use of this device.

See individual sterile package label for contents.

**SINGLE-USE DISPOSABLE MEDICAL DEVICE. CONTENTS ARE  
STERILE IF PACKAGE IS UNOPENED AND UNDAMAGED.  
DO NOT RESTERILIZE**

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO USE BY OR ON  
THE ORDER OF A PHYSICIAN.**

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**Response™ CV  
CARDIOVERSION ELECTROPHYSIOLOGY  
CATHETER WITH LUMEN**

**INSTRUCTIONS FOR USE**

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## 1 DEVICE DESCRIPTION

Response CV Catheter is a cardioversion electrophysiology catheter featuring ten distal EP electrodes, one proximal coil electrode, and a lumen.

## 2 INDICATIONS FOR USE

The SJM Cardioversion Response™ (CV) Electrophysiology Catheter when used with the SJM CV Electrophysiology Extension Cable and SJM Switchbox System is indicated for use in the invasive evaluation of cardiac arrhythmias and can be used for intracardiac cardioversion of atrial tachyarrhythmias.

## 3 CONTRAINDICATIONS

- Electrophysiology studies are contraindicated when arrhythmogenic conditions are present, including but not limited to, electrolyte abnormality, acute ischemia, drug toxicity, and hyperthyroidism.
- Electrophysiology studies are contraindicated for patients with unstable cardiac conditions, including but not limited to, acute myocardial infarction, unstable angina, and hemodynamic instability.
- Do not use as an ablation catheter.
- Do not use in the left atrium and left ventricle.
- Do not use in patients who cannot tolerate anticoagulation therapies.
- Do not use for cardioversion or defibrillation of ventricular arrhythmias.

## 4 WARNINGS AND PRECAUTIONS

### 4.1 WARNINGS

- Serious injury or death may result if energies above 50 joules are delivered through this device. DO NOT use this device to deliver energies above 50 joules.

### 4.2 PRECAUTIONS

- DO NOT alter this device.
- Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- Only physicians thoroughly trained in the techniques of intracardiac recording, stimulation and cardioversion should use this device.
- This device should only be used with equipment that complies with international safety standards.
- Individual patient anatomy and physician technique may require procedural variations.

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- Do not use a guidewire over maximum diameter specified on package label.
- Use an 8F or larger hemostasis introducer for catheter insertion.
- Flush the lumen, side-port and stopcock with heparinized normal saline prior to use in the patient.
- Ensure patient is properly anticoagulated prior to performing cardioversion with this device.
- Use the minimum amount of defibrillator output required for therapeutic effect during internal cardioversion. Defibrillator output must be limited to 50 joules or less during internal cardioversion.
- Not intended for use with high-pressure injection equipment.
- Misuse of this catheter and accessories may result in serious complications.
- Single-use disposable medical device. Contents are sterile if package is unopened and undamaged. Do not re-sterilize.
- Store in a cool, dark, dry place.

## 5 ADVERSE EVENTS

### 5.1 OBSERVED ADVERSE EVENTS

The Response CV system was studied in 173 patients undergoing cardioversion and / or catheterization procedures, of this group: 82 patients received internal cardioversion and 91 patients received external cardioversion. The number of patients with major adverse events as defined by the clinical protocol was: 7 from the internal patient group and 6 from the external patient group. A detailed breakout of the observed adverse events is provided in **Table 1**. There were no procedure related deaths reported in the pivotal study.

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**Table 1: Observed Adverse Events**  
All Patients Treated (N = 173)

Major Complications	Total # per Major Complication Category	Subjects Randomized to Internal Cardioversion, N (%) N=82	Subjects Randomized to External Cardioversion, N (%) N=91
Atrial Tachycardia	1	-	1 (1.10%)
Ventricular Fibrillation	1	1 (1.22%)	-
Pulmonary Edema	1	1 (1.22%)	-
Possible Air Embolism	1	-	1 (1.10%)
Nausea and Vomiting	6	4 (4.88%)	2 (2.20%)
Vaso-vagal response during blood draw	2	-	2 (2.20%)
Hypotension	1	1 (1.22%)	-
<b>Total</b>	13	7 (8.54%)	6 (6.59%)
<b>Unique Patients</b>	13	7 (8.54%)	6 (6.59%)
<b>Complication-free rate [95% C.I.]</b>		<b>91.46% [83.2%,96.5%]</b>	<b>93.41% [86.20%,97.42%]</b>
<b>z-statistic</b>		-0.015	
<b>p-value</b>		0.49	

## 5.2 POTENTIAL ADVERSE EVENTS

Adverse effects (in alphabetical order) which may be associated with catheterization and internal cardioversion include:

- Anaphylaxis (allergic reaction) with breathing problems, drop in blood pressure, and possibly death
- Angina (chest discomfort)
- Arrhythmia (irregular heartbeat)
- Arterial/venous thrombosis (clot formation on the inside wall of the artery at the entry site)
- AV fistula (a communication between the artery and vein at the site of catheter insertion)
- Back pain and/or groin pain
- Cardiac perforation (hole in the lining of the heart)
- Hematoma formation (bruise or bleeding into body tissue) in groin area
- Hypotension (fall in blood pressure)
- Infection
- Myocardial infarction (heart attack)
- Pericardial effusion or cardiac tamponade (collection of blood in lining of the heart)
- Pneumothorax (an accumulation of air or gas in the pleural space)
- Significant blood loss which may lead to blood transfusion
- Thrombotic events including stroke and pulmonary emboli

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- Unintentional complete heart block requiring a pacemaker
- Vessel wall or valvular trauma which may lead to surgical repair

## 6 CLINICAL STUDY

The clinical study was a prospective, acute, multi-center, randomized design in which outcomes for the primary study endpoints were compared to a control group using the current clinical procedure, external cardioversion. If the randomized treatment failed, retreatment with the initial treatment (after supplemental medication) or crossover to the alternative treatment group was permitted. The crossover and retreatment data were analyzed separately from the initial randomized treatment data.

### 6.1 STUDY BLIND

Because of the procedural differences in the test and control procedures, the study could not be double blinded. The patient randomization was blinded until immediately prior to the procedure.

### 6.2 STUDY RESULTS

The Response CV Internal Cardioversion system has been shown to be a safe and effective method for the intracardiac (internal) cardioversion of atrial fibrillation. The Response CV Catheter can be used during electrophysiology studies to map and pace cardiac arrhythmias and be used for intracardiac cardioversion of atrial tachyarrhythmias. Benefits associated with the Response CV Catheter can be less pain or discomfort from the lower energy levels of the internal shock.

One hundred and seventy-three patients were enrolled and randomized for treatment: 82 patients were initially randomized to receive Response CV (internal cardioversion) and 91 patients were initially randomized to receive the external cardioversion.

[ Results of the clinical study provide valid scientific evidence and reasonable assurance that the Response CV Catheter system is safe and effective when used in accordance with its labeling. The safety of the device has been demonstrated through the low incidence of complications in patients treated with the investigational device. ]The effectiveness of the device has been demonstrated through the successful internal cardioversion of patients with AF as compared to patients with AF who were externally cardioverted in this study. Analysis of safety data demonstrated comparable results between the

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test and control groups. Safety (**Table 1 above**) was defined as the incidence of major complications. Efficacy (**Table 2 below**) was defined as the success rate for cardioversion for the therapy to which the subjects were initially randomized.

**Table 2: Efficacy**  
Total Patients Evaluated (N=168)

<b>Efficacy Initial Randomization</b>	<b>Response CV N (%) N total = 79</b>	<b>External CV N (%) N total = 89</b>
<b>Success</b>	76 (96.2 %)	61 (68.5%)
<b>Failure</b>	3 ( 3.8%)	28 (31.5%)
<b>Success Rate Estimate [95% C.I.]</b>	96.20% [89.30, 99.21%]	68.54% [57.83%, 77.97%]
<b>z –statistic</b>	-5.91	
<b>p-value</b>	1.7E-9	

## 7 PATIENT SELECTION AND TREATMENT

The safety and effectiveness of internal cardioversion has not been established in:

- Asymptomatic patients;
- Patients who are pregnant;
- Nursing mothers; or
- In pediatric patients

## 8 SUGGESTED DIRECTIONS FOR USE

Follow general EP laboratory procedure for general patient management.

- Advance this catheter into the right atrium and coronary sinus using standard insertion techniques.
- Place the electrophysiology catheter in the coronary sinus so the distal EP electrodes are located in the coronary sinus/great cardiac vein and the proximal coil rests against the lateral wall of the right atrium.
- Once this device is properly positioned, ensure that the patient is properly anticoagulated prior to continuing the procedure.
- The SJM Electrophysiology Catheter with Lumen incorporates a central lumen, which may be used for the infusion of medications or radiographic contrast agents. Additionally, a guidewire may be inserted through the lumen to assist in catheter positioning.



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- Confirm proper catheter placement. Perform diagnostic or cardioversion procedures per appropriate Cardioversion Switchbox Instructions For Use.

## 9 HOW SUPPLIED

The Response CV Catheter is only available with 10 ring electrodes, 1 cardioversion coil, and a central lumen. See product catalog and / or package label for reorder numbers and product description.

### 9.1 PACKAGING

The Response CV Catheter is supplied sterile. The catheter is placed into a thermoformed plastic tray designed to protect the catheter during shipping and handling. The tray is placed into a Tyvek® and Mylar® pouch and heat sealed.

### 9.2 STORAGE AND SHELF-LIFE

The catheters must be stored in a cool, dark, dry place. All catheters are labeled with a three year expiration date.

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# 10 SYMBOL DEFINITIONS

SYMBOL	- Definition of symbols.
	- Store in a cool, dark, dry place.
	- Lot Number
	- Reorder Number or Catalog Number
	- Contents of the package
	- Caution, consult accompanying documents.
	- Useable length of the device.
	- Inter-Electrode Spacing (mm)
	- Maximum guidewire outside diameter that can be used with this device.
	- Minimum introducer inside diameter that can be used with this device.
	- Sterilized using ethylene oxide.
	- Single use device. Do not resterilize.
	- Date of manufacture or Sterilized on.
	- Use before

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